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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0840]

Hospira, Inc.; Withdrawal of Approval of a New Drug Application for DEXTRAN 70

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for DEXTRAN 70 (6% Dextran 70 and 0.9% NaCl or/5% Dextrose 500 mL Glass Bottle) held by Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045. Hospira, Inc., has notified the Agency in writing that this product is no longer marketed and has requested that approval of the application be withdrawn.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

Jonathan McKnight,

Center for Biologics Evaluation and Research (HFM-17),

Food and Drug Administration,

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Rockville, MD 20852,

301-827-6210.

SUPPLEMENTARY INFORMATION: Hospira, Inc., has requested that FDA withdraw approval of NDA 080-819, DEXTRAN 70 (6% Dextran 70 and 0.9% NaCl or/5%

Dextrose 500 mL Glass Bottle) under the process in § 314.150(c)(21 CFR 314.150(c)), stating that the product is no longer marketed. By its own request, Hospira, Inc., has also waived its opportunity for a hearing provided under § 314.150(a).

Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Biologics Evaluation and Research, by the Commissioner of Food and Drugs, approval of NDA 080-819, DEXTRAN 70 [6% Dextran 70 and 0.9% NaCl or/5% Dextrose 500 mL Glass Bottle], and all amendments and supplements thereto, is hereby withdrawn, effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: August 9, 2012.

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Karen Midthun,
Director,
Center for Biologics Evaluation and Research.

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